

AMENDMENTS TO THE SPECIFICATION:

At page 11, please amend paragraph [0016] as follows:

[0016] The size of the container 10 is not narrowly critical and is dependent upon the cell sample volume that is desired to be collected and preserved. For example, a typical size for the container 10 may have an internal volume of between 100 μ l to 10 ml. The container 10 can be constructed using art-disclosed methods and is commercially available (e.g., ~~Vacutainer~~ VACUTAINER[®] Plus ~~Plastic Tubes~~ plastic tubes with ~~Hemogard Closure~~ HEMOGARD[™] closures available from Becton Dickinson and Company located in Franklin Lakes, New Jersey; the evacuated sample collection tube described in U.S. Patent No. 5,860,937, which is incorporated by reference). Of course, it should be understood that a wide range of changes and modifications can be made to the preferred embodiment described above for the container 10.

At pages 13-14, please amend paragraph [0019] as follows:

[0019] The preferred fixative agent 26 is a heterocyclic urea (e.g., diazolidinyl urea (known as DU), imidazolidinyl urea (known as IDU) or a mixture thereof). The most preferred fixative agent is diazolidinyl urea. The suitable amount of the fixative agent 26 for the claimed subject matter is that effective to fix or stabilize the cells 20 without causing significant dilution of the cells 20 (i.e., not clinically significant), and thereby allowing the cells 20, stored with the compounds 22, to be directly analyzed by a flow cytometer. For example, in a preferred embodiment, diazolidinyl urea is the fixative agent 26 and its concentration weight/volume is preferably about less than about 1 g/ml, more preferably less than about 0.75 g/ml, and most preferably less than about 0.5 ~~g/ml~~ g/ml concentration of solution of DU before blood sample is added.

At pages 14-18, please amend paragraph [0021] as follows:

[0021] Additional compounds may optionally be added as one of the compounds 22 in the device 100. Such additional and optional compounds may include: cell permeabilizing agents for substantially gaining access to intracellular analytes/epitopes and/or for lysing red blood cells; proteins that substantially protect the cells during processing and/or substantially reduce non-specific binding of probes; serum/lipoproteins that substantially protect cells

during processing and/or substantially reduce non-specific binding of probes; RNase inhibitors which substantially inhibit digestion of RNA and/or substantially maintain RNA integrity; nucleic acid stabilizers which substantially inhibit the degradation of nucleic acids and nucleic acid containing compounds; amino acids / polypeptides which substantially enhance binding of probes/antibodies to epitopes and/or substantially increases the observable signal; fixatives which substantially preserve cell integrity especially for permeabilization agents, and may preserve some epitopes; anticoagulants which substantially decreases clotting of red blood cells, chelates calcium and / or may help maintain WBC integrity/viability; protease inhibitors which substantially decreases degradation of protein epitopes; antioxidants/ reducing agents which substantially prevent hemolysis of red blood cells and/ or substantially prevent oxidation of peptides, and/ or substantially maintain epitopes; nucleic acid dyes that generally serve to label/identify nucleic acid; carbohydrates which substantially maintain cellular integrity and/or osmolarity; and, polyacrylic acids which substantially enhance the binding of probes and/or antibodies to epitopes; and /or substantially increases signal. One of skill in the art should be able to determine the usefulness and quantities of such optional compounds by routine testing and knowledge of the art. Within multiple specific embodiments the above additional and optional compounds may be more specifically include: Cell permeabilizing agents such as: DMSO (Dimethyl Sulfoxide), Ethylene glycol, Polyethylene glycol, Glycerin, Cellosolves (ethylene glycol dimethyl ether) (phenoxyethanol), ~~Triton~~ TRITON[®] X 100, ~~Triton~~ TRITON[®] X 705 (non-ionic detergents), 1-methyl-2-pyrrolidinone, ~~Tween~~ TWEEN[®] 20, ~~Tween~~ TWEEN[®] 40 (non-ionic surface active agents), ~~Brij~~ BRIJ[®] 35 (detergent), Polyoxyethylene ether (Polyox) , Sodium cholate, Ethylene oxide polymers, Monensin, Monactin, Pentachlorophenol, 2,4 dinitrophenol, saponin, SDS (sodium dodecyl sulfate); Proteins such as: Biotin, Albumins (egg, bovine), Gelatin, and similar such compounds as should be known to one of skill in the art; RNase inhibitors such as: human placenta derived RNase inhibitor, and similar such compounds should be known to one of skill in the art; Nucleic acid stabilizers such as: Guanidinium hydrochloride, Polycations such as Polyethylenimine), and similar such compounds as should be known to one of skill in the art; Amino acids/polypeptides such as: Glutamic acid, Glycine, Aspartic acid, and similar such compounds as should be known to one of skill in the art; Fixatives such as: Aldehydes (formaldehyde and glutaraldehyde),

Alcohols (ethanol, methanol), and similar such compounds as should be known to one of skill in the art; Anticoagulants such as: EDTA (Ethylene Diamine Tetra acetic acid.), and similar such compounds as should be known to one of skill in the art; ACD (Acid Citrate Dextrose), Heparin, and similar such compounds as should be known to one of skill in the art; Protease Inhibitors such as: EDTA, PMSF (phenyl methyl sulfonyl fluoride), AEBSF (2-Aminoethyl benzene sulfonyl fluoride), and similar such compounds as should be known to one of skill in the art; Antioxidants/ Reducing agents such as: ~~Trolox~~ TROLOX[®] antioxidant, ~~a-tocopherol~~ α -tocopherol, ~~β -mercaptoethanol~~ β -mercaptoethanol, and similar such compounds as should be known to one of skill in the art; Nucleic Acid Dyes such as: DAPI (Diamidino 2-phenylindole), Propidium Iodide, Fluorescein diacetate, and similar such compounds as should be known to one of skill in the art; Carbohydrates such as: Sugars (sucrose), cellulose, and similar such compounds as should be known to one of skill in the art. It should be appreciated that the above specific listings of compounds may contain a measure of overlap, which recognizes the sometimes-overlapping function of certain specific compounds. One of skill in the art should understand and appreciate this aspect of the disclosure.

At pages 19-20, please amend paragraph [0023] as follows:

[0023] The device 100 may be included in a kit of the claimed subject matter containing components 32 (not shown) conventionally used to collect and analyze the cells ~~30~~ 20 such as alcohol swab, gauze, tube holder, tourniquet, glove, other cell collection tube (with or without conventional cell analysis additives inside such tube), needle (with hub, part of a syringe assembly including barrel and plunger, or with wings connected via a hub and tubing to another needle for delivery to the device 100 or other collection tubes), lancet, adhesive strip, syringe, test strip (allowing the cells 20 to flow directly onto a glass or plastic strip containing reagents for cell analysis), glass or plastic strip containing reagents for cell analysis (e.g., immunoassay), packaging means (e.g., plastic bag, compartmentalized plastic enclosure, and the like) to store the desired components 32 and the device 100, and packaging means to transport the cells 20 stored in the device 100 after collection. It is preferred that the packaging means and any other components 32 that may become in

physical contact with the cells 20 be sterilized and the packaging means is constructed to maintain this sterile environment.

At pages 20-21, please amend paragraph [0027] as follows:

[0027] The mechanism by which the fixative agent 26 provides the desired tissue and cell membrane stabilization is not known for certain. It is believed that the fixative agent binds in some fashion to the cell membrane or tissue. This hypothesis is drawn because many members of the active agent are known disinfectants, which kill bacteria by binding to cell structure. This is not a full explanation of the mechanism responsible for the results of the claimed subject matter since many other disinfectants such as ~~KATHON~~ KATHON® disinfectants and ~~OMADINE~~ OMADINE® disinfectants fail to provide tissue and cell stabilizing effects.